

## Impact Health Policy Weekly

### Framing the Week

The House and Senate are both in recess until after Labor Day. During this Congressional break, we are taking the opportunity to provide in-depth analysis of policies under consideration for a potential lame duck package, which culminate with the release of the Impact Health Policy Partners Lame Duck and Election Preview memo in September. To start, we are highlighting pharmacy benefit manager (PBM) reform, prescription drug patent reform, and legislation to address generic drug shortages.

#### **PBM Reform**

Last year, the House and the Senate both advanced several bills aimed at addressing PBMs, including legislation to increase PBM transparency, prohibit spread pricing in Medicaid, and delink PBM reimbursement from the cost and utilization of the drug, among other reforms. This year, lawmakers remain focused on advancing PBM reform, primarily as an offset to other health care priorities, such as extending the COVID-19 telehealth flexibilities. Most recently, the House Committee on Oversight and Accountability convened its [third hearing](#) on the role of PBM in prescription drugs markets, which coincided with the Committee's release of its [report](#) on the impact of PBM practices on health care costs ([Impact summary](#)).

**Impact Health's chart here features the primary PBM bills still under consideration, as well as a compendium of PBM bills introduced in the 118<sup>th</sup> Congress.** As PBM reform is an area that has received bipartisan support, it is likely that some combination of provisions from the bills previously advanced could be included in a potential lamed duck package, especially if they are scored by the Congressional Budget Office (CBO) to generate savings. Provisions that have received the most bipartisan support appear to be the transparency requirements and prohibiting spread pricing in Medicaid. The delinking provisions, which are featured in recent House telehealth legislation ([H.R. 8261](#) and [H.R. 7623](#)) face less bipartisan support.

#### **Prescription Drugs**

While the Administration remains focused on implementing the prescription drug provisions of the Inflation Reduction Act, including the forthcoming release of the maximum fair price for the initial price applicability year 2026 of the Medicare Drug Price Negotiations program, Congress has expressed interest in advancing legislation aim at patent reform. Last month, the Senate passed [S. 150](#), the Affordable Prescription for Patients Act of 2023, which prohibits products hopping by drug manufacturers. The Congressional Budget Office estimates that this bill would generate [\\$2.4 billion in savings](#) over ten years. The Senate Judiciary has also advanced [S. 148](#), the Stop STALLING Act, and [S. 142](#), the Preserve Access to Affordable Generics and Biosimilars Act, which are estimated to save [\\$300 million](#) and [\\$1.2 billion](#),

respectively. Such legislation could be featured in a potential lame duck package, if lawmakers seek to offset the cost of other health care priorities.

### **Generic Drug Shortages**

Amid reports of ongoing generic drug shortages, the [House](#) and [Senate](#) held hearings to examine such shortages, as well as related supply chain challenges, and potential policy solutions. Following the hearings, the Senate Finance Committee released a [white paper](#), and subsequent [discussion draft](#), aimed at addressing persistent drug shortages. The Biden Administration also released a [white paper](#), as well as a [request for information](#) to address the shortages. With no legislation advanced at this time, it is unlikely that provisions to address drug shortages will be included in a potential lame duck package.

### Regulatory Update

The Office of Management and Budget (OMB) is reviewing the following rules:

#### **Medicaid**

- **Drug Rebate Program** – The [final rule](#) would establish requirements related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP). In addition, it finalizes beneficiary protections, as well as MDRP program integrity and administration changes (June 2024).

#### **Private Insurance**

- **ACA Marketplace** – The [proposed rule](#) would set payment parameters and provisions related to the risk adjustment programs; cost-sharing parameters; and user fees for issuers offering plans on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It would also provide additional standards for several other ACA programs (September 2024).

#### **Other Topics:**

- **Healthcare System Resiliency and Modernization** – The [proposed rule](#) would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers (was set for December 2023).
- **Tobacco Control** – The [final rule](#) would prohibit the sale of tobacco products to persons younger than 21 years of age (was set for April 2024).
- **Retail Pharmacy Standards** – The [final rule](#) would require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10 (was set for February 2024).

## This Week in Health Policy

### Mon. (8/5)

- **9:30am – ASPE Meeting: Alzheimer’s Research** – The Assistant Secretary for Planning and Evaluation (ASPE) holds a meeting of the Advisory Council on Alzheimer’s Research, Care, and Services. The Council provides advice on how to prevent or reduce the burden of Alzheimer’s disease and related dementias (ADRD) on people with the disease and their caregivers. During the meeting, the Advisory Council subcommittees will present their recommendations for adoption by the full Advisory Council. [Details.](#)
- **12:00pm – HITAC Meeting: Annual Report Workgroup** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. [Details.](#)

### Tue. (8/6)

- **11:00am – HITAC Meeting: HTI-2 Proposed Rule Task Force** – HITAC holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. This meeting of Group 1 will be focusing on: New public health certification criteria. [Details.](#)

### Wed. (8/7)

- **11:00am – HITAC Meeting: HTI-2 Proposed Rule Task Force** – HITAC holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. This meeting of Group 2 will be focusing on: Patient, Provider, and Payer APIs. [Details.](#)

### Thurs. (8/8)

- **11:00am – HITAC Meeting: HTI-2 Proposed Rule Task Force** – HITAC holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. This meeting of Group 3 will be focusing on: Information Blocking Enhancements. [Details.](#)

### Additional Multi-Day Events

- **Aug 7-Aug 8 – HRSA Meeting: Nursing Workforce Issues** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Nurse Education and Practice for the nursing workforce (e.g., nursing shortage, distribution, supply, and access) nursing practice improvement, nursing education, nursing work environment and support, and other Title VIII program activities. The Council will review the initial draft of its 20th Report Recommendations. The Council will also receive presentations from the Centers for Medicare and Medicaid Services (CMS) and the American Association of Nurse Anesthesiology. [Details.](#)

- **Aug 8-Aug 9 – HRSA Meeting: Heritable Disorders in Newborns/Children** – HRSA holds a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children. The agenda includes a presentation on types of screening that are a part of the standard of care in a clinical setting, and other program updates. [Details.](#)

### Featured Analysis

- **Impact Regulatory Outlook: Spring 2024 Unified Agenda** – In the Policy Hub Insight Bank [here.](#)
- **Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions** – In the Policy Hub Insight Bank [here.](#)
- **Impact Mental Health Legislative Update** – In the Policy Hub Insight Bank [here.](#)
- **Impact Roundup of Behavioral Health Administrative Actions** – In the Policy Hub Insight Bank [here.](#)
- **Impact Chart of Key Provisions of Legislative Proposals on Health Care Price Transparency Requirements** – In the Policy Hub Insight Bank [here.](#)

### Congressional Lookback

#### Thurs. (8/1)

- **The Senate Commerce, Science, and Technology Committee** advanced a series of bipartisan artificial intelligence focused bills. [Details.](#)

#### Weds. (7/31)

- **The Senate Homeland Security and Governmental Affairs Committee** [voted 10-1](#) to advance three bipartisan cybersecurity bills, paving the way for full Senate consideration. [Details.](#)
- **The Senate HELP Committee** convened a [markup](#) of three bipartisan bills to strengthen services for older Americans, bolster programs and research for autism spectrum disorder, and advance traumatic brain injury programs. [Details.](#)

### Regulatory Lookback

#### Thurs. (8/1)

- **CMS** released the FY 2025 IPPS and LTCH PPS [final rule.](#) [Details.](#)

#### Weds. (7/31)

- **CMS** released the FY 2025 SNF PPS [final rule.](#) [Details.](#)
- **CMS** released the FY 2025 IRF PPS [final rule.](#) [Details.](#)
- **CMS** released the FY 2025 IPF PPS [final rule.](#) [Details.](#)

**Tues. (7/30)**

- **CMS** released the FY 2025 hospice payment rate update [final rule](#). [Details](#).
- **The CRS** issued a [report](#) listing appellate decisions since October 2021 that upheld agency actions under Chevron. [Details](#).

**Mon. (7/29)**

- **CMS** released the [projected 2025 Part D base premiums](#), as well as information on a [voluntary Part D Premium Stabilization Demonstration](#). [Details](#).

**Comment & Application Deadlines**

- **August 12:** The CFPB issued a [proposed rule](#) aimed at eliminating medical bills from most credit reports. [Details](#).
- **August 15:** CMS is seeking [nominations](#) to the Advisory Committee on Immunization Practices. [Details](#).
- **August 17:** CMS released a [notice of funding opportunity](#) for the Expanding Access to Women's Health Grant. [Details](#).
- **August 20:** SAMHSA is [seeking](#) applications for the Women's Behavioral Health Technical Assistance Center (Women's BH TAC) program for fiscal year 2024. [Details](#)
- **August 26:** CMS issued the CY 2025 home health prospective payment and rate update [proposed rule](#). [Details](#).
- **August 26:** CMS released its CY 2025 end-stage renal disease (ESRD) prospective payment system (PPS) [proposed rule](#). [Details](#).
- **September 2:** CMS released an [ICR](#) for the Negotiation Data Elements and Drug Price Negotiations Process for IPAY 2027 of the Medicare Drug Price Negotiation Program. [Details](#).
- **September 7:** The FDA released [draft Q&As](#) to address misinformation about medical devices and prescription drugs. [Details](#).
- **September 9:** CMS released the CY 2025 MPFS [proposed rule](#). [Details](#).
- **September 9:** CMS released the CY 2025 OPPTS/ASC [proposed rule](#). [Details](#).
- **September 20:** CMS released a [notice of funding opportunity \(NOFO\)](#) for the Transforming Maternal Health (TMaH) Model. [Details](#).
- **September 26:** The FDA issued [draft guidance](#) entitled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." [Details](#).
- **September 30:** The CDC is [seeking nominations](#) for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details](#).
- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details](#).